

**EXPEDITED PROCEDURE EXAMINING GROUP: 3761**

Docket: 11842/US/2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

First Named Inventor:	Sandra M. Maclean	Confirmation No.:	5239
Appln. No.:	10/664,236	Examiner:	Anderson, Catherine L.
Filing Date:	September 17, 2003	Group Art Unit:	3761
Title:	<b>Miscarriage Care Package</b>		

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

**APPEAL BRIEF**

TABLE OF CONTENTS

<u>Contents</u>	<u>Page</u>
(i) Real Party in Interest .....	3
(ii) Related Appeals and Interferences .....	4
(iii) Status of Claims. ....	5
(iv) Status of Amendments. ....	6
(v) Summary of Claimed Subject Matter .....	7
(vi) Grounds of Rejection to be Reviewed on Appeal .....	9
(vii) Argument .....	10
(viii) Claims Appendix .....	38
(ix) Evidence Appendix .....	43
(x) Related Proceedings Appendix .....	44

(i) **REAL PARTY IN INTEREST**

The present application has not been assigned.

(ii) RELATED APPEALS AND INTERFERENCES

None.

(iii) **STATUS OF CLAIMS**

Claims 1, 25-31, 35-42 are herein appealed.

Claims 2-9, 32-34 have previously been canceled.

Claims 1, 10-31, 35-42 are pending.

Claims 10-24 are withdrawn.

Claims 1, 25-31, 35-37, and 40 stand rejected under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement.

Claims 1 and 25-31 stand rejected under 35 U.S.C 102(b) as anticipated by or, in the alternative, under 35 U.S.C 103(a) as obvious over U.S. Patent No. 4,917,238 to Schumacher (“Schumacher”).

Claims 35-37 stand rejected under 35 U.S.C 103(a) as unpatentable over U.S. Patent No. 4,917,238 to Schumacher in view of U.S. Patent No. 6,434,762 to Gordon (“Gordon”).

Claims 38-42 stand rejected under 35 U.S.C 103(a) as unpatentable over U.S. Patent No. 4,917,238 to Schumacher in view of U.S. Patent No. 6,622,856 to Gallo et al. (“Gallo”).

(iv) STATUS OF AMENDMENTS

No claim amendments were filed subsequent to the final rejection.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

The presently appealed claims are generally directed toward a care kit or package for use by women undergoing, or expected to undergo, a miscarriage. As claimed, the miscarriage kit may include at least one under pad/bed liner that may be used to protect furniture or other surfaces as a woman undergoes the miscarriage. The kit may also include at least one specimen pan designed and adequate for receiving human tissue as the woman undergoes the miscarriage. The kit may also include at least one container for holding fetal remains for legal disposition. The kit may also contain additional items for use in assisting the woman emotionally, mentally, and/or physically as she undergoes, or prepares to undergo, a miscarriage.

Specifically, Claim 1 recites a miscarriage kit (10) comprising: at least one under pad/bed liner (14) configured to be positioned on a surface (e.g., paragraph 50), the under pad/bed liner (14) having a bottom layer and a top layer (e.g., paragraph 50), wherein the top layer is designed to absorb bodily fluids (e.g., paragraph 51), and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer (e.g., paragraph 50); at least one sanitary napkin (22, 24); at least one towel (26, FIG. 8, e.g. paragraph 54); at least one pair of gloves (28, FIG. 9); at least one specimen pan for receiving human tissue (16, FIGS. 3A and 3B); and at least one container for holding fetal remains for legal disposition (18, FIG. 4, e.g. paragraphs 55-56).

Claim 35 recites a miscarriage kit (10) comprising: at least one under pad/bed liner (14) configured to be positioned on a surface (e.g., paragraph 50), the under pad/bed liner (14) having a bottom layer and a top layer (e.g. paragraph 50), the top layer is designed to absorb bodily fluids (e.g., paragraph 51), and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer (e.g., paragraph 50); at least one sanitary napkin (22, 24); at least one towel (26, FIG. 8, e.g., paragraph 54); at least one pair of gloves (28, FIG. 9); at least one specimen pan (16, FIGS. 3A and 3B), wherein the specimen pan (16) is configured to fit inside the rim of a toilet (e.g., paragraph 52) and further includes an upper rim configured to allow the upper rim to rest atop the toilet rim (e.g., paragraph 53), the specimen pan having an opening positioned and sized to receive fluids and human tissue from a miscarriage (e.g., paragraph 54), and wherein the specimen pan is comprised of a durable material (e.g., paragraph 52); and

wherein the specimen pan provides a measurement guide for measurement of fluid loss (e.g., paragraph 53); and at least one container for holding fetal remains for legal disposition (18, e.g., paragraph 55-56), wherein the container is opaque (e.g., paragraph 55).

Claim 38 recites a miscarriage kit (10) comprising: at least one under pad/bed liner (14, e.g., paragraphs 50-51); at least one sanitary napkin (22, 24, e.g. paragraphs 58-60); at least one towel (26, e.g. paragraph 61); at least one pair of gloves (28, e.g. paragraph 62); at least one specimen pan for receiving human tissue (16, e.g. paragraphs 52-54); and at least one container for holding fetal remains for legal disposition (18, e.g. paragraphs 54-56); and at least one thermometer (34, paragraph 66).

(vi) **GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Whether Claims 1, 25-31, 35-37, and 40 are unpatentable under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement.

Whether Claims 1 and 25-31 are unpatentable under 35 U.S.C 102(b) as anticipated by or, in the alternative, under 35 U.S.C 103(a) as obvious over U.S. Patent No. 4,917,238 to Schumacher (“Schumacher”).

Whether Claims 35-37 are unpatentable under 35 U.S.C 103(a) over U.S. Patent No. 4,917,238 to Schumacher in view of U.S. Patent No. 6,434,762 to Gordon (“Gordon”).

Whether Claims 38-42 are unpatentable under 35 U.S.C 103(a) over U.S. Patent No. 4,917,238 to Schumacher in view of U.S. Patent No. 6,622,856 to Gallo et al. (“Gallo”).

(vii) ARGUMENT

(A) PRELIMINARY STATEMENT

Appellants/Applicants respectfully submit that claims 1, 25-31, 35-37, and 40 comply with the written description requirement of 35 U.S.C. 112, first paragraph. Additionally, that claims 1 and 25-31 are not anticipated by Schumacher, because each and every limitation of the independent claims is not disclosed in Schumacher.

Further, Applicants submit that the Examiner has not established a *prima facie* case of obviousness as to claims 1, 25-31, and 35-42. Schumacher, the primary, and in some cases the *only*, reference relied upon for the obviousness rejections is non-analogous art because, with respect to Applicants' claimed invention, the functions of the field of endeavor of the disclosed inventions as a whole are different, and the problems in the fields of endeavor are different. But even if, for the sake of argument, it is accepted that Schumacher is analogous art, the asserted combination of Schumacher modified in view of Gordon, or Schumacher modified in view of Gallo would render the modified inventions unsuitable for their intended purpose, and as such the combinations are improper. Finally, even if deemed proper, the combination of references relied upon by the Examiner does *not* disclose, teach, or suggest *all* of the claim limitations as required under 35 U.S.C. § 103(a). Accordingly, Applicants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of claims 1, 25-31, and 35-42.

(B) DESCRIPTION OF THE APPLIED ART

Claims 1 and 25-31 stand rejected under 35 U.S.C 102(b) as anticipated by or, in the alternative, under 35 U.S.C 103(a) as obvious over Schumacher. Claims 35-37 stand rejected under 35 U.S.C 103(a) as unpatentable over Schumacher in view of Gordon. Claims 38-42 stand rejected under 35 U.S.C 103(a) as unpatentable over Schumacher in view of Gallo.

The Schumacher Reference

Schumacher teaches a waste cleanup kit for disposing of human waste “in a manner which abates risk of transfer of infectious diseases to the person cleaning the waste.” (Col. 1, lns. 34-37). Additionally, the Schumacher cleanup kit is designed to be used to clean up a one-time mess and then be thrown away. (Col. 1, lns. 37-40). More specifically, the cleanup kit is intended to be used for cleaning up and disposing of human waste, such as human vomit, blood, feces and the like (Col. 2, lns. 6-7), which has been expelled for example in a public facility, such as a school, a restaurant, a public transportation vehicle, such as an airplane or bus, a daycare center, or other environment. (Col. 1, lns. 29-31). Typically, a person other than the person who expelled the human waste would be responsible for cleaning up the waste, thus the concern with avoiding the transfer of communicable diseases. (Col. 1, lns. 33-36). “The most significant anticipated use is for disposal of human vomit which may contain viruses for infectious disease such as Hepatitis B or AIDS.” (Col. 4, lns. 10-13).

The kit may contain a cardboard box 12, plastic bags with closure means 53, 54, such as a twist tie 55, and a pair of disposable plastic gloves 57, 58. (Col. 2, lns. 44-53). The kit may further contain a package 59 of absorbent material 62 in a clear flexible pouch 60 with a press locked end 61. The absorbent material is a granular material, such as a mixture of clay, sawdust and deodorant. (Col. 2, lns. 57-60). “The amount of granular material included in the pouch is selected for an anticipated one time clean-up chore.” (Col. 2, lns. 62-63). The operator of the kit is instructed to open the box, and then open the absorbent containing pouch 60 and sprinkle or spread the granular material 62 over the waste. (Col. 4, 15-22).

The kit may also include a collapsible scoop 80 (see FIG. 3) and a scraper 90. The scoop includes a waste receiving surface 81’ that is formed by leaving one side of a rectangle-shaped disposable box open. (FIG. 3; col. 3, lns. 50-58). The scraper 90 is a flat sheet of corrugated cardboard. (Col. 3, ln. 66). After pouring the granular material over the waste, an operator is instructed to put on the disposable gloves, grab the scoop and scraper in opposing hands and scrape the waste and granular material into the scoop. (Col. 4, lns. 21-26). Next, the operator is instructed to place the scoop, its contents, the scraper, and the granular material pouch into a plastic bag and twist-tie it shut. (Col. 4, 27-28).

The kit may also include a plastic bottle 64 and cap 65 for containing a metered amount of chlorine solution. (Col. 3, lns. 2-3). Preferably the bottle is pre-filled with a concentrated amount of sodium hypochlorite. (Col. 3, lns. 3-6). The amount of sodium hypochlorite is selected such that a user can fill the remainder of the volume of the bottle with water to dilute the sodium hypochlorite. (Col. 3, lns. 8-11). The amount of solution the bottle may hold is selected such that there is sufficient solution for a one-time disinfection of an area contaminated by human waste, in this case, 6 to 7 fluid ounces. (Col. 3, lns. 11-16). The bottle may have a pour spout 69 to direct the stream of disinfectant to the desired area. (Col. 3, lns. 22-23). After placing the scoop, scraper and waste material in a plastic bag and using a twist-tie to close it, the operator is instructed to pour the chlorine solution from the bottle onto the spill area and allow it to set for approximately ten minutes. (Col. 4, lns. 32-35).

The kit may also include “preferably three disposable towels 50, 51, 52 (preferably absorbent paper towels or the like).” (Col. 2, lns. 45-47). Once the chlorine solution has set, “the operator is next instructed to use disposable towels 50 through 52 to wipe up the diluted chlorine solution from the spill area and then to place all items including the disposable gloves in the second bag 54.” (Col. 4, lns. 35-38).

#### The Gordon Reference

The Gordon reference is directed to an apparatus for collecting human stool that is easy to use and permits for a contamination-free stool sample. (Gordon, Abstract). The apparatus attaches to a toilet seat and includes a disposable strip 12 and a stool receptacle 14. “In preferred embodiments, the sealable stool receptacle is a plastic zip-lock bag, and the disposable strip is formed of paper.” (Col. 2, lns. 4-6). In the center of the strip 12 there is an opening 18 for stool collection. The apparatus “supports a sealable stool receptacle in an appropriate position relative to a toilet seat.” (Col. 1, lns. 43-44). The apparatus is designed to be placed on a toilet seat such that it only collects stool and not other contaminants “whether from the patient’s hands, urine leakage, toilet bowl water. . .” (Col. 3, lns. 32-38).

The Gallo Reference

The Gallo reference is directed to a kit for relieving the discomfort of infants. Examples of discomfort include fever, pain, congestion, skin irritation and irritability. The Gallo kit may include an inner container for holding items, which may include, cold medicine, gas relief products, fever and pain relieving products, and diaper rash relief products. (Gallo, Abstract; claims 1-3).

(C) CLAIMS 1, 25-31, 35-37, AND 40 COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT UNDER 35 U.S.C 112, FIRST PARAGRAPH

The Examiner rejected claims 1, 25-31, 35-37, and 40 as including subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Examiner asserted that the claim recitation of an underpad having a bottom layer that protects the surface from bodily fluids that soak through the top layer or is impermeable is not supported in the present specification. (Office Action, page 5).

Independent claims 1 and 35 as amended recite, “at least one under pad/bed liner configured to be positioned on a surface, the under pad/bed liner having a bottom layer and a top layer, wherein the top layer is designed to absorb bodily fluids, and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer.” Claim 40 recites, “[t]he miscarriage kit of claim 1, wherein the bottom layer of the under pad/bed liner is impermeable to bodily fluids.” The specification supports “bottom layer protects . . .” and “impermeable” either explicitly or implicitly. As set forth in the MPEP, the inquiry is whether one skilled in the art would find that the applicant was in possession of the invention as claimed:

While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure . . . The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. (MPEP § 2163 (I)(b)).

Applicants respectfully submit that one skilled in the art would understand that the applicant was in possession of an invention wherein a bottom layer of an under pad/bed liner is impermeable.

The specification describes an underpad/bed liner with a “pad backing [which] is made from a thick polypropylene and has a non-skid feature to ensure the product stays in place. The bed-liner has an absorbent padding that is adhered to one side of the backing. This absorbent padding is centered onto the backing with a 1.5" frame surrounding the pad. In one embodiment, the disposable underpad/bed-liner is mint green with a white absorbent pad and is offered by

First Quality Products, Inc. of McElhattan, PA.” (Specification, paragraph 50). The specification goes on to state that the purpose of the underpad/bed liner is “to assist in keeping the woman's surroundings sanitary by absorbing bodily fluids. For example, the underpad/bed-liners are useful where a woman chooses to miscarry in a bed, chair, sofa or other physical surroundings. The bed-liner helps to reduce worries about blood or fluid soaked bedding or fabrics and the discomfort of washing or cleaning these after miscarriage.” (Specification, paragraph 51). In order to both absorb bodily fluids, as disclosed in the specification, and also to reduce worries about blood and fluid soaked bedding, the underpad/bed liners must both absorb bodily fluids and protect the surface onto which the liner is placed. Accordingly, an absorbent layer and a fluid impermeable layer are disclosed and taught in the specification. Applicants respectfully submit that any argument that one skilled in the art would not understand such underpad/bed liner to include an impermeable layer or surface is per se unreasonable.

The specification supports an under pad/bed liner having a bottom surface and a top surface. Paragraph 50 of the present specification reads “[t]he bed-liner has an absorbent padding that is adhered to one side of the backing.” This explicitly states the dual layer nature of the underpad /bed-liner, with one layer that is both absorbent and padded and a further backing, or bottom, layer.

The claim recites that a “bottom layer protects the surface from bodily fluids that soak through the top layer.” This limitation is supported at least by paragraph 51 of the present specification which indicates that “[t]he bed-liner helps to reduce worries about blood or fluid soaked bedding or fabrics and the discomfort of washing or cleaning these after miscarriage.” At least because a woman may choose to “miscarry in a bed, chair, sofa, or other physical surroundings,” but also because a miscarriage often can take between several hours and several days to complete, this would lead one skilled in the art to reasonably understand that the underpad/bed liner protects the surface upon which it is placed from the possibility of blood flow that soaks through the top absorbent layer. (Specification, paragraph 51).

Claim 40 recites an under pad/bed liner that has a bottom layer that is “impermeable to bodily fluids.” The Examiner has argued that this language is not supported by the specification because “[p]olypropylene materials such as nonwoven fabrics are not inherently liquid

impermeable, and are often permeable to liquids. Therefore, the claim limitation disclosing a liquid impermeable bottom surface is not supported by the specification as originally filed, and constitutes new matter.” (Office Action dated March 17, 2008 (“Previous Office Action”), page 4). For purposes of support in the specification, polypropylene can be impermeable. While polypropylene may be impermeable or permeable depending on configuration, the key point is that polypropylene *may be impermeable*. Accordingly, because the specification discloses polypropylene, and polypropylene may be impermeable, the present disclosure supports polypropylene being impermeable. Further, in the context of the present specification, a polypropylene layer would be understood to be impermeable, at least because a fluid permeable backing would not fulfill the objective of the underpad/bed liner as it would not protect the surface on which it is placed from fluids that soak through the upper layer. Thus, the specification provides support for a polypropylene layer that is impermeable to bodily fluids.

Finally, the specification discloses the Prevail® brand under pads from First Quality Products, Inc. to be a suitable underpad/bed liner. (Specification, paragraph 50). A product selection guide can be viewed at: <http://www.firstquality.com/default.aspx?pageid=121>. (See Applicants’ Response to Previous Office Action, Appendix A). The Prevail® brand under pads are the only underpad/bed liners that First Quality Products, Inc. sells that meet the other descriptions in the patent specification. First Quality Products describes this pad as “[f]or bed or chair protection.”

For at least the preceding reasons, the current specification supports the claims as amended that recite an underpad/bed liner that is “designed to absorb bodily fluids . . . wherein the bottom layer protects the surface from bodily fluids that soak through the top layer,” as recited in claims 1, 25-31, 35-37, and an underpad/bed liner that is “impermeable to liquids,” as recited in claim 40. Withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is thus respectfully requested.

(D) CLAIMS 1 AND 25-31 ARE NEITHER ANTICIPATED BY, NOR OBVIOUS OVER SCHUMACHER (U.S. PATENT NO. 4,917,238)

Schumacher does not disclose each limitation of independent claim 1, either alone, or in view of itself. As such, claims 1 and 25-31 are patentable over Schumacher.

1. CLAIMS 1 AND 25-31 ARE NOT ANTICIPATED BY SCHUMACHER

Schumacher does not disclose each and every element of independent claim 1, at least because Schumacher does not disclose an underpad/bed liner, a specimen pan, and/or a container for holding fetal remains for legal disposition. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (MPEP § 2131). Schumacher accordingly cannot support an anticipation rejection of the claims.

Independent Claim 1

I. Schumacher Does Not Disclose, Teach, or Suggest an Underpad/Bed Liner

Schumacher simply does not disclose an underpad/bed liner. Particularly, Schumacher does not disclose an underpad/bed liner as defined in Appellant’s specification. Independent claim 1 recites in relevant part:

“at least one underpad/bed liner configured to be positioned on a surface, the underpad/bed liner having a bottom layer and a top layer, wherein the top layer is designed to absorb bodily fluids, and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer.”

The Specification recites that one purpose of the underpad/bed liner is to “assist in keeping the woman’s surroundings sanitary by absorbing bodily fluids. For example, the

underpad/bed-liners 14 are useful where a woman chooses to miscarry in a bed, chair, sofa or other physical surroundings. The bed-liner 14 helps to reduce worries about blood or fluid soaked bedding or fabrics and the discomfort of washing or cleaning these after miscarriage.” (Specification, paragraph 51).

In the most recent Final Office Action of September 17, 2008, (“Office Action”) the Examiner asserts that Schumacher discloses “a pad 52 having an absorbent surface (column 2, lines 45-47).” (Office Action, page 5). The pad 52 of Schumacher to which the Examiner refers is one of three disposable towels, which are “preferably absorbent paper towels or the like.” (Schumacher, col. 2, lns. 55-57). In response to Applicants’ arguments that a paper towel does not anticipate an underpad/bed liner, the Examiner stated simply that “the disposable towel is fully capable of functioning as a bed-liner, and therefore fulfills the claimed limitation.” (Office Action, page 2).

Applicants note that, to support an anticipation rejection, a reference must disclose each element of the claim *in as complete detail* as recited in the claim. *MPEP 2131, citing Richardson v. Suzuki Motor co.*, 868 F.2d 1226, 1236, 9 USPQ2d1913, 1920 (Fed. Cir. 1989). Applicants respectfully submit that Schumacher does not disclose an underped/bed liner at all, much less in as complete detail as claimed. Applicants again argue that the paper towels of Schumacher cannot reasonably be used to anticipate an underpad/bed liner “configured to be positioned on a surface,” and “having a bottom layer and a top layer, wherein the top layer is designed to absorb bodily fluids and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer,” as claimed. Schumacher does not teach or disclose a disposable towel with more than one layer, much less a top layer and a bottom layer, wherein the top layer is designed to absorb bodily fluids and wherein the bottom layer protects the surface upon which it is placed from bodily fluids that soak through the top layer. Because the disposable towel of Schumacher does not teach or disclose a top and bottom layer as recited in independent claim 1, Schumacher does not anticipate claim 1.

“[T]he meaning of a prior art reference requires analysis of the understanding of an artisan of ordinary skill . . . To anticipate, ‘[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.’” *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323 (Fed. Cir. 2008) (quoting *Scripps Clinic & Res. Found. v. Genetech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991)). One

reasonably skilled in the art would understand the difference between a disposable towel and an underpad/bed liner. An underpad/bed liner may be used preventatively for containing fluids over an extended period of time and for protecting surfaces from being damaged or soiled by bodily fluids. A paper towel, on the other hand, may be used for cleaning up messes that have already occurred and may then be easily disposed of. Typically, several paper towels may be used to clean up a single mess, as each single paper towel may be easily soaked through depending on the size of the mess to be cleaned. Disposable paper towels do not generally contain the absorbency necessary to absorb the bodily fluids expelled during a miscarriage and at the same time protect the undersurface in the same way as an underpad/bed liner specifically configured to perform this function would.

The specification of Schumacher and of the present disclosure bears this out in more detail, and the differences between the elements become even more evident when evaluated “in light of the [whole] specification.” (Claims are to be read in light of the specification (See MPEP § 2111)). Schumacher discloses an invention, whereby an operator using the invention is instructed to use the disposable paper towels to “wipe up the diluted chlorine solution from the spill area” and then place them in a bag to be disposed of. (Schumacher, col. 4, lns. 35-37). Schumacher teaches the following steps for using the cleanup kit: scattering an absorbent material onto the waste to be cleaned; scooping up the waste and the absorbent material; placing the waste and absorbent material in a disposable bag; squirting a chlorine solution onto the spill area; and then, using the disposable towels to wipe up the diluted chlorine solution from the spill area. (Schumacher, col. 4, lns. 17-44).

Schumacher does not teach using paper towels to clean up or collect human waste, as paper towels would be inadequate and inappropriate for that task because using paper towels to collect the human waste material would not prevent the spread of infectious disease. Instead, the paper towels are used to wipe up the diluted chlorine solution from an area that has already had the waste removed. Thus, the context for paper towels in Schumacher is that they are intended for use in wiping up the chlorine solution from an otherwise mostly cleaned area, and they are only to be used once. In contrast, the current disclosure teaches that the use of the disclosed underpad/bed liners may “reduce worries about blood or fluid soaked bedding or fabrics and the discomfort of washing or cleaning these after a miscarriage.” (Specification, paragraph 51). In the case of Schumacher, the disposable towels are specifically *not* meant to clean up bodily

waste, but rather to wipe up the remaining chlorine solution and then be thrown away, whereas in the case of the present disclosure the underpad/bed liner is configured specifically to have a top layer that absorbs bodily fluids and a bottom layer that protects the surface on which the liner is placed. One skilled in the art would not have a reasonable expectation that a disposable towel would be capable of both absorbing the bodily fluid and also protecting the underlying surface upon which it was placed. In any event, Schumacher does not teach or disclose an underpad/bed liner as recited in claim 1.

Additionally, the Examiner's reading of the claims violates the fundamental canon of claim differentiation in interpreting claims. In addition to reciting an underpad/bed liner, claim 1 also recites "at least one towel." The Examiner's argument that the towel in Schumacher is equivalent to an underpad/bed liner in the current application ignores the separate claimed element of a towel in the current application. Because there are two separate and distinct elements in independent claim 1, a "towel" and an "underpad/bed liner," the elements must be distinct. Accordingly, the Examiner's assertion that the "disposable towel" of Schumacher is the same as the "underpad/bed liner" of the present disclosure is not a reasonable construction of the current claims. "A claim construction that gives meaning to all of the terms of the claim is preferred over one that does not do so." (*Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005)).

## II. Schumacher Does Not Disclose, Teach, or Suggest a Specimen Pan for Receiving Human Tissue

Schumacher does not disclose a specimen pan for receiving human tissue as recited in independent claim 1. What Schumacher discloses is a "scoop," which Examiner equates with the specimen pan of the present disclosure. The Examiner asserts that Schumacher discloses a "scoop/specimen pan 80. . . [t]he specimen pan is fully capable of holding fetal remains." (Office Action, page 6).

The scoop 80 of Schumacher is a collapsible disposable device intended to be used to receive the bodily waste and absorbent material which a person scrapes into it. The scoop is configured like a rectangular box with one side missing, such that the waste material may be scraped into the scoop.

Claim 1, in contrast, recites “a specimen pan for receiving human tissue.” As discussed in the specification of the present disclosure, the specimen pan may be used for the following:

“assisting in collecting and/or calculating blood or other bodily fluid loss for recording purposes. Fluid loss may be monitored and recorded to determine whether safe limits have been exceeded. The specimen pan can also be used to collect tissue and/or fetal remains, sparing the additional trauma of retrieving fetal remains from an unsanitary toilet. Once the bodily fluids, tissue and/or fetal remains are collected in the pan, they may be transferred to a spill-proof, sanitary container. . .” (Specification, paragraph 54).

The Examiner has stated that “a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.” (Office Action, page 3). Further, the Examiner has continued to assert that “the scoop of Schumacher is sized and shaped such that material such as human tissue may be received therein.” (Office Action, page 3).

The scoop taught by Schumacher cannot properly be construed as a specimen pan, as claimed. The Schumacher scoop is defined such that one side is not enclosed so that bodily waste which has already been expelled may be “scooped” into the scoop from an area such as a floor of a public facility. In contrast, the claimed specimen pan does not, and could not, have such a gap. (See, for example, Specification, FIGS. 3A and 3B). The specimen pan cannot have a gap that is necessarily present in the scoop of Schumacher and still fulfill its purpose of receiving and containing human tissue and fluid as they are expelled from the body, as discussed in the present disclosure. Attempting to use the scoop 80 of Schumacher to function as a specimen pan would result in bodily fluids and tissue leaking out of the open end of the scoop. As such, the Schumacher scoop and the specimen pan are structurally different, and thus, even according to the Examiner’s reasoning, Schumacher does not disclose a specimen pan as recited in the current claims.

### III. Schumacher Does Not Disclose, Teach, or Suggest a Container for Holding Fetal Remains for Legal Disposition

Schumacher does not teach or disclose at least one container for holding fetal remains for legal disposition, as recited in independent claim 1. The Examiner asserts that Schumacher discloses a “container 64.” (Office Action, page 6). Further, that “the container 64 is fully capable of holding fetal remains.” (Office Action, page 6).

The plastic bottle and cap of Schumacher, which the Examiner refers to as “container 64,” is a “plastic bottle and cap for containing a metered amount of chlorine solution.” (Schumacher, col. 3, lns. 2-3). The bottle is specifically sized to hold 6-7 fluid ounces. (Schumacher, col. 3, lns. 15-16).

The plastic bottle 64 of Schumacher does not disclose a container for holding fetal remains, as the plastic bottle 64 of Schumacher is not configured to contain the amount of fetal remains accompanying a miscarriage. The present disclosure requires that the container hold at least 300 grams of fetal remains and material. (See Dean Affidavit, page 2, submitted with Applicants’ Response to Final Office Action of September 11, 2007). The affidavit submitted pursuant to 37 C.F.R. 1.132, filed January 7, 2008, set forth the average amount of fetal remains expelled during miscarriage and explained that Schumacher would not be large enough to hold that amount of material. Accordingly, Schumacher does not disclose a container for holding fetal remains.

Additionally, the Schumacher plastic bottle does not disclose a container for holding fetal remains because the plastic bottle of Schumacher has a very narrow neck. (FIG. 1, element 64). The plastic bottle of Schumacher is configured to hold a chlorine solution that may be squeezed onto an area where a spill has occurred and been picked up, in order to disinfect the area. The Examiner has provided no guidance as to how the bottle could hold fetal remains, or how the fetal remains could be placed in the bottle, given that the neck is so narrow.

The Examiner asserts that Applicants rely on the size of the container when Applicants argue the plastic bottle of Schumacher does not anticipate the container for holding fetal remains of the present disclosure. (Office Action, page 3). Further, the Examiner asserts that because the size of the container is not claimed, the size limitation may not be read into the claims. (Office Action, page 3). Claim 1 recites a container for holding fetal remains. As such, in order to anticipate claim 1, the prior art reference must disclose a container that is capable of holding

fetal remains. The plastic bottle of Schumacher is not capable of holding fetal remains at least because, as discussed above, the bottle is not large enough to contain the expected amount of fetal remains, and also because it is not clear how, or if, fetal remains could be forced into the plastic bottle, given the plastic bottle's very narrow neck. Because Schumacher does not disclose a container for holding fetal remains, Schumacher does not anticipate independent claim 1.

#### IV. Schumacher Does Not Disclose, Teach, or Suggest a Sanitary Napkin

Claim 1 recites at least one sanitary napkin, in addition to at least one towel, and at least one underpad/bed liner. Schumacher discloses a cleanup kit including, among other things, "three disposable towels, 50, 51, 52 (preferably paper towels or the like)." (Schumacher, col. 2, lns. 45-46). The three disposable towels are not distinguished in Schumacher, one from the other, in any way. The Examiner has asserted that one of the disposable towels 52 discloses a pad having an absorbent surface, while another of the identical disposable towels 50 discloses a disposable absorbent towel, and yet still another of the identical disposable towels 51 discloses a sanitary napkin. (Office Action, page 5). The common understanding of sanitary napkin may be found in any dictionary, for instance, online at dictionary.com as being, "a pad of absorbent material, as cotton, worn by women during menstruation to absorb the uterine flow." The specification of the present disclosure confirms that the common understanding of "sanitary napkin" is what is indeed intended (for example, "[t]he large sanitary napkins 22 are backed with plastic and have two adhesive strips on the backside to allow for proper placement in undergarments." (Specification, paragraph 58)). One skilled in the art could not reasonably understand a disposable paper towel to be the same as a sanitary napkin.

Accordingly, Schumacher does not anticipate the present disclosure at least because Schumacher does not disclose an underpad/bed liner, a specimen pan for receiving human tissue, a container for holding fetal remains for legal disposition and/or a sanitary napkin. For all of these reasons, Schumacher does not anticipate the present disclosure, and accordingly claim 1 is patentable over Schumacher.

Dependent Claims 25-31

Claims 25-31, also rejected as anticipated by Schumacher, depend from claim 1 and are patentable over Schumacher for the reasons set forth above with reference to claim 1, and also in view of their additional recitations.

**2. CLAIMS 1 AND 25-31 ARE NOT OBVIOUS OVER SCHUMACHER ALONE**

The Examiner has not provided sufficient grounds for the obviousness rejection of Schumacher in view of *only* Schumacher. As such Applicants have been unable to respond fully to the rejection. Nonetheless, the present claims are not obvious over Schumacher in light of only Schumacher, because Schumacher is not pertinent art on which to predicate an obviousness rejection.

Independent Claim 1

**I. Insufficient Grounds Provided for Obviousness Rejection**

The Examiner has maintained the 103 rejection from previous Office Actions, finding the current disclosure obvious over Schumacher alone, stating that “Claims 1 and 25-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schumacher (4,917,238).” (Office Action, page 5). The Examiner has failed to provide the grounds on which the present application is obvious in light of only Schumacher, despite explicitly requesting this information in Applicants’ response to the Previous Office Action. (Applicants Response the Previous Office Action, pages 15-17).

The Examiner has not met the standard set out under 35 U.S.C. § 103 that “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious . . . to a person having ordinary skill in the art . . .” (Office Action, page 6, See also *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (U.S. 2007)).

While the MPEP and numerous court decisions specifically direct examiners to provide clear reasons for rejections on obviousness grounds, neither the current Office Action, nor the previous Office Actions, state the grounds for the obviousness rejection in light of *only* Schumacher. (See MPEP § 2141; *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (U.S. 2007) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006))). In the last two Office Actions, the Examiner discusses Schumacher in terms of anticipation, and Schumacher in view of Gordon, and in the most recent Office Action, Schumacher in view of Gallo, but the Examiner does not give any explanation for the rejection of the present claims on obviousness grounds over *only* Schumacher.

The Applicants question whether the Examiner may be relying on a previous Office Action argument regarding obviousness only in view of Schumacher. (Office Action of September 11, 2007, pages 3-4). The Applicants suspect this may be the case based on the fact that substantially the same text and arguments are used in the current and previous Office Actions as the basis for the novelty rejection. (See Office Action, pages 5-6, and Previous Office Action, pages 4-5). The Applicants respectfully note that mixing novelty and obviousness analysis is discouraged by the courts. (See *TorPharm Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1326 FN3 (Fed. Cir. 2003) (stating that while lack of novelty is the epitome of non-obviousness, “novelty and nonobviousness are separate concepts that are best kept analytically distinct.”)).

Nonetheless, the Examiner’s analysis in the Office Action of September 11, 2007, fails to resolve the *Graham* inquiries as recommended by the MPEP. (See MPEP § 2141 (II), “The question of obviousness must be resolved on the basis of [the *Graham*] factual determinations.”). Furthermore, the Examiner’s arguments fail to state the grounds upon which the rejection is based with any clarity to allow the Applicants to respond. (See MPEP § 706, “The goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity.”). Applicants submit that the Examiner has not made out a *prima facie* case of nonobviousness of the present disclosure over *only* Schumacher. (See MPEP § 2142, “If the examiner does not produce a *prima facie* case, the applicant is under no obligation

to submit evidence of non-obviousness.”). Nonetheless, Applicants provide arguments below that independent claim 1 is not obvious in light of only Schumacher.

## II. Schumacher Is Not Pertinent Prior Art

The first determination that must be made in order to determine obviousness or nonobviousness is the “scope and content of the prior art . . .” (*Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

The analogous-art test requires that the Board show that a reference is either in the field of the applicant's endeavor or is reasonably pertinent to the problem with which the inventor was concerned in order to rely on that reference as a basis for rejection. References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art. (*In re Kahn*, 441 F.3d 977, 987 (Fed Cir. 2006) (citing *In re Oetiker*, 977 F.2d 1443, 1447 (Fed.Cir.1992))).

### a. *The Fields of Endeavor Are Different*

The claimed invention is not in the same field of endeavor as Schumacher, nor is Schumacher reasonably pertinent to the problem the current Applicants seek to solve. Schumacher's field of endeavor is stated directly in the patent:

#### 1. Field of the Invention

This application pertains to a cleanup kit. More particularly, this application pertains to a kit for cleaning up body substances while abating infection from diseases carried by the substances. (Schumacher col. 1, lns. 8-12).

In contrast, the field of invention of the current disclosure is as follows:

The present invention relates to medical supplies and means and methods of treating and preparing a medical patient. More specifically the present invention relates to obstetric supplies and obstetric means and methods of treating and preparing an obstetric patient. (Specification, paragraph 2).

At least because Schumacher deals with cleaning supplies and the current invention deals with medical supplies, the current application is not in the same field of endeavor as Schumacher.

b. *The Problems in the Fields of Endeavor Are Different*

Schumacher is not reasonably pertinent to the problem being solved by the current application. “A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commanded itself to an inventor’s attention in considering his problem.” (*In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1380 (Fed. Cir. 2007) (quoting *In re Clay*, 966 F.2d 656, 659 (Fed.Cir.1992))). The claimed invention deals with the long-felt need for “preparing a woman, her partner, and/or caregiver for a miscarriage and for caring for the woman.”

On the other hand, Schumacher discloses an objective of:

“provid[ing] a kit for cleaning up human waste in a manner which abates risk of transfer of infectious diseases to the person cleaning the waste. Another object of the present invention is to provide such a cleanup kit which may be *used for a single instance of waste cleanup and readily disposed.*” (Schumacher, col. 1, lns. 34-40)(emphasis added).

A single use kit for cleaning up bodily waste in a local convenience store or other public place that is then immediately disposed of does not “logically command itself” to the problem of properly preparing and dealing with a miscarriage. A miscarriage is not a once-and-done event such as the problem that Schumacher is directed toward. Furthermore, Schumacher does not address the problem of disposal of a fetus, as well as providing a means for determining whether there is an incomplete miscarriage requiring immediate medical attention. One reasonably skilled in the art would not look to Schumacher when trying to solve the problem of caring for a woman going through a miscarriage. Because Schumacher and the current disclosure are directed to different fields of endeavor as well as to different problems in their respective fields, Schumacher is not pertinent prior art upon which to predicate an obviousness rejection.

### III. Claims 1 and 25-31 Are Not Obvious over Schumacher Alone

The Examiner seems to have predicated the obviousness rejection on the Examiner's view that the Schumacher invention could *clean up* the miscarriage remains. (See Office Action dated September 11, 2007, page 3-4; see also Previous Office Action, page 5). Even assuming that this is true (which the Applicants assert it is not) this is not the proper question to answer. The question is not whether you can use the prior art to accomplish the same function as the claimed invention in question, but whether "the differences between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art ..." (35 U.S.C. § 103) (emphasis added). According to the Examiner's viewpoint a new mechanical invention could never be patented so long as another invention in the prior art would be useful for the same function.

The Applicants assert that the rejections on obviousness grounds are improper at least because they take too narrow of a view of the current application. "The proper approach to the obviousness issue must start with the claimed invention *as a whole*." (*Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1448 (Fed. Cir., 1984) (citing 35 U.S.C. § 103)(emphasis in the original)). Furthermore, "[i]t is immaterial to the issue, however, that all of the elements were old in other contexts. What must be found obvious to defeat the patent is the claimed combination." (*Id.*).

The MPEP provides that "[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences *themselves* would have been obvious, but whether the claimed invention as a *whole* would have been obvious." (MPEP §2141.02) (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983)). The Applicants respectfully assert that the invention (in addition to significant deficiencies discussed with respect to the rejections under 102(b)), when viewed as a whole is not obvious from the Schumacher invention as a whole. The primary intent in Schumacher and the problem that Schumacher is trying to solve is minimizing the spread of disease during the one-time clean up

of another person's human waste. (Schumacher, col. 1, lns. 19-25). In contrast, the current invention is directed to providing a woman with all reasonably necessary items before, during, and after a miscarriage. This typically involves not just the one-time cleanup of bodily waste, but dealing with sporadic fluid excretions, and the fetal tissue which must be disposed of according to law in a certain way (See MINN. STAT. § 144.1521, 2008 MINN. LAWS CH. 326 HF 3222(4), Submitted with Applicants' Response to Previous Office Action as Appendix A (medical facilities must have in place a policy for informing a woman of available options for fetal disposition when the woman experiences a miscarriage.)). The Applicants' invention solves these problems by, for example, providing an "underpad /bed liner," "a specimen pan," and a "container for holding fetal remains for legal disposition," all of which are recited in claim 1. Schumacher discloses none of these items and only teaches a one-time cleanup of human waste by someone other than the person who had the accident, not a combination of items to be used by a woman over the course of hours or days as she experiences a miscarriage.

Furthermore, contrary to the Examiner's assertions that the Schumacher kit can be used to solve the current problem of miscarriage care, the differences between the Schumacher kit and the claimed kit are significant and one of ordinary skill in the art would not know to modify Schumacher to achieve the current application. (See *Graham v. John Deere Co.*, 383 U.S. 1, 17 ("differences between the prior art and the claims at issue are to be ascertained;")). While a person having ordinary skill in the art is "a person of ordinary creativity, not an automaton," and courts should give credit to such persons to fill in the gaps, the differences between the Schumacher patent and the current application are not mere gaps, but a wide chasm. (*KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742).

It would be a stretch for a person of ordinary skill in the art to start with the one-time disposable cleanup kit of Schumacher directed to avoiding disease transmission in order to address the problem of a miscarriage. The modifications to Schumacher necessary to arrive at the current kit that solves the miscarriage problem are significant. The current application discloses, among other things, an underpad/bed liner, a sanitary napkin, a specimen pan for receiving human tissue and a container for holding fetal remains for legal disposition. None of these elements are present (or suggested, or even hinted at) in Schumacher, either expressly or implicitly.

The Applicants submit that the common elements of Schumacher and the present application are extremely minimal (a pair of gloves and a towel). While the Examiner tries to rely on a purported similarity of elements such as a scoop, a cardboard box, or a bottle (pre-filled with sodium hypochlorite) that hypothetically (according to the Examiner) could serve the purposes of a specimen pan or a container for holding fetal remains, this argument is not only legally insufficient as already explained, but the Schumacher items are actually incapable of fulfilling the functions of the items of the present disclosure. For instance, the cardboard box and scoop are made from cardboard or some other necessarily flexible and cheap material that can be folded and immediately disposed of. (See Schumacher, col. 1, ln. 30 – col. 3, ln. 61). Such materials are unusable for the purposes of dealing with a miscarriage, as many times a miscarriage can last multiple days; as such using such materials is neither sanitary, nor feasible. Additionally, none of the items of Schumacher can serve the purpose of holding a fetus for legal disposition. The Schumacher bottle has a narrow neck that will not permit a miscarried fetus to be inserted into the bottle without a great deal of effort, if at all. But even if the miscarried fetus could fit through the neck of the bottle, in many cases the bottle would not be large enough to contain the fetus. (See Schumacher, Figure 1, item 64). The bottle of Schumacher is sized to hold 6-7 fluid ounces, far below the average sized fetus at 20 weeks gestation. The bottle of Schumacher is at least 30% too small to hold an *average* sized fetus at 20 weeks. (See Schumacher, col. 3, lns. 15-16, Dean affidavit, page 2 (average sized fetus at 20 weeks is 300 grams – which is 10.5 ounces)).

Finally, modifying the items of Schumacher to disclose the items of the present disclosure would render the Schumacher kit “unsatisfactory for its intended purpose.” The current disclosure as claimed in claims 1, 25-31, and 35-42, is not obvious over Schumacher. (MPEP §2143.01(V) (“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.”) (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984))). Specifically, to arrive at the present claims, the towel of Schumacher would need to be an “underpad/ bed liner,” the scoop of Schumacher would need to be a “specimen pan,” and the bottle would need to be a “container for holding fetal remains for legal disposition.”

Modification of a towel to make it a multi-layer absorbent pad that protects the surface it is positioned on renders it unsuitable for use in Schumacher's waste disposal kit. An underpad/bed liner would increase the size and cost of the kit due to the increased size and thickness of the underpad/bed liner. Further, having a layer that protects a surface on which it is placed, or an impermeable layer, makes the liner generally unsuitable for use in a context wherein the liner is used to wipe up a cleaning solution.

Modification of the "scoop" of Schumacher to form a "specimen pan," as claimed would make the scoop unsatisfactory for its intended purpose. The scoop necessarily has an open side, as discussed above. A specimen pan for holding human tissue is necessarily a closed device used to contain material. Were the scoop to be modified to have four closed sides, the scoop would no longer function as a scoop.

Further, as previously noted, modifying the Schumacher bottle such that it could contain a miscarried fetus of average size at 20 weeks gestation, the bottle would have to be significantly larger than the bottle of Schumacher. But Schumacher teaches that the 6-7 fluid ounces that the Schumacher bottle can hold is all that is needed for disinfecting a spill area. (Schumacher, col. 3, lns. 11-15). There would be no reason to increase the size of the bottle. Further, as shown in Schumacher's FIG. 1, the bottle has a narrow neck and is not designed to receive a fetus. The bottle design of Schumacher, including the narrow neck, facilitates pouring the liquid solution contained in the bottle onto the spill area. Increasing the neck size to permit receipt of a fetus would render the bottle unsuitable for directing a fluid stream toward a specific place. (Schumacher, col. 3, lns. 20-25).

#### IV. Independent Objective Proof of Non-obviousness Was Inappropriately Not Considered

The Examiner inappropriately refused to consider independent objective proof of nonobviousness submitted by Applicants. Once the Patent Office issues a rejection on obviousness grounds, "Office personnel should consider all rebuttal arguments and evidence presented by applicants." (MPEP §2145). This includes declarations of non-obviousness by those skilled in the art. (MPEP §2145, see also *In Re Beattie* 974 F.2d 1309, 1313). The Applicants

submitted an expert affidavit from one reasonably skilled in the art describing the invention as “non-obvious,” and further stating that the Schumacher kit could not reasonably be used to provide miscarriage support for a woman for at least two reasons: 1) Schumacher is directed toward a one-time clean up kit for bodily fluids, whereas a miscarriage is typically a several day event; and 2) nothing disclosed in Schumacher would enable a woman experiencing a miscarriage to dispose of the fetal remains properly. The Examiner dismissed the affidavit for “lack of documentary evidence.” In response, the Applicants submitted the following references documenting specifically the size of a fetus at 20 weeks: <http://www.babycenter.com/average-fetal-length-weight-chart>. (Submitted with Applicants’ Response to Previous Office Action, as Appendix B). The Applicants submit that fetal size at a gestational age is a scientific figure and is easy for one skilled in the art to determine. The Examiner did not explain why the expert affidavit was not considered with respect to the one time use versus multiple use issue. The Applicants thus argue that the Examiner inappropriately dismissed the 1.132 affidavit regarding obviousness. Because it would not be obvious to modify Schumacher in light of only Schumacher to disclose the elements of independent claim 1, independent claim 1 is not obvious over Schumacher.

The Applicants thus respectfully assert that independent claim 1 is neither anticipated by, nor obvious over, Schumacher. Accordingly, claim 1 is patentable over Schumacher.

Dependent Claims

Because claims 25-31, 35-37, and 40 depend from claim 1, they are allowable for at least the same reasons, and further in view of their additional recitations.

Reconsideration and allowance are respectfully requested.

(E) CLAIMS 35-37 ARE NOT OBVIOUS OVER SCHUMACHER IN VIEW OF GORDON (U.S. PATENT NO.6,434,762)

Independent claim 35 recites that the at least one specimen pan is configured to fit inside the rim of a toilet and further includes an upper rim configured to allow the upper rim to rest atop the toilet rim, the specimen pan having an opening positioned and sized to receive fluids and

human tissue from a miscarriage, and wherein the specimen pan is comprised of a durable material; and wherein the specimen pan provides a measurement guide for measurement of fluid loss.

The Examiner asserts that “Schumacher discloses a kit with a specimen pan 80 as disclosed above with respect to claim 1. Schumacher *does not expressly disclose* the pan is configured to fit inside the rim of a toilet.” (Office Action, page 6).

In the Applicants’ response to the previous Office Action, Applicants explicitly requested clarification of whether Examiner was asserting that Schumacher implicitly or inherently discloses a specimen pan configured to fit inside the rim of a toilet. (Response to Previous Office Action, page 23). The Examiner refused to provide clarification on this point, and instead only repeated verbatim the same rejection, in the same format, without clarification or response to Applicants’ arguments. (Office Action, page 7). Accordingly, Applicants take it that Applicants’ stated assumption was correct, namely that it was the Examiner’s intention to state that Schumacher does not disclose a specimen pan configured to fit inside the rim of a toilet, explicitly, implicitly, or inherently.

#### 1. GORDON FAILS TO CURE THE DISCLOSURE DEFICIENCIES OF SCHUMACHER

The Examiner asserts that “Gordon discloses a stool/waste collecting apparatus 10 secured to a toilet seat (column 2, lines 46-55; figures 1-3).” While Gordon may disclose a stool collecting apparatus, Gordon does not disclose a “specimen pan having an opening positioned and sized to receive fluids and human tissue from a miscarriage,” as recited in claim 35. One difference between the collecting apparatus of Gordon and the specimen pan of the present application are the respective locations for positioning on the toilet seat. Gordon is specifically configured to “collect a stool sample.” (Gordon, col. 1, ln. 36). As such, the stool collecting apparatus of Gordon must be positioned below the user’s anus. In contrast, in the present disclosure, the specimen pan must be located below the vaginal area to collect the human tissue or fetal remains, as recited in claim 35. Gordon specifically cautions against collection of urine as it might contaminate the sample. (See Gordon, col. 3, lns. 33-39). Placement of the Gordon

apparatus below the vagina would inevitably render the Gordon apparatus unusable, as it would contaminate the stool sample.

## 2. GORDON IS NOT PROPERLY COMBINED WITH SCHUMACHER

Again, the Applicants reiterate that “[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences *themselves* would have been obvious, but whether the claimed invention as a *whole* would have been obvious.” (MPEP §2141.02) (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983)). The Applicants assert that it would not be obvious to combine a waste *cleanup* kit with a stool *collection* kit to create a miscarriage *care* kit.

The Examiner does not make clear how exactly the scoop of Schumacher would be modified in light of Gordon. The Schumacher scoop is a collapsible and disposable scoop. Gordon discloses a disposable strip formed of paper with a sealable stool receptacle attached (Gordon, col. 2, lns. 4-6). In any event, even if it were clear how Schumacher could be modified in light of Gordon, Schumacher teaches away from a modification of this nature. Schumacher, as has been discussed extensively above, is directed to *cleaning up* human waste and avoiding transmission of disease during the clean up process. Clearly, there would be no need to *clean up* anything if the person expelling the waste in Schumacher were able to make it to a toilet in the first place. There would certainly be zero reason to *collect* and preserve any of the human *waste* disclosed in Schumacher, as the whole point of Schumacher is to dispose of the human waste, while minimizing the threat of contamination. Modifying the Schumacher scoop to fit inside of a toilet would be counterproductive and/or pointless in light of the purpose of Schumacher. To the extent the person could make it to a toilet to expel the human waste, there would be no need to *clean up* the human waste. And to the extent that minimizing contagious disease transmission is a goal of Schumacher, if a person could expel their bodily waste into a toilet, it would be unsanitary to attempt to collect the waste or impede its disposal path. As such, modifying Schumacher in light of Gordon would render Schumacher unsatisfactory for its intended purpose. (MPEP §2143.01(V) (“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation

to make the proposed modification.”)(citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

Because modifying Schumacher in light of Gordon would render Schumacher unsatisfactory for its intended purpose, and because Gordon does not remedy the disclosure deficiencies of Schumacher, independent claim 35 is thus allowable over Schumacher alone and/or Schumacher combined with Gordon.

Dependent Claims

Claims 36 and 37 depend from claim 35 and are thus patentable for at least the same reasons and further in light of their additional recitations.

Reconsideration and allowance are thus respectfully submitted.

(F) CLAIMS 38-42 ARE NOT OBVIOUS UNDER 35 U.S.C. 103(a) OVER SCHUMACHER IN VIEW OF GALLO ET AL. (U.S. PATENT NO. 6,622,856)

Regarding independent claim 38, the Examiner asserts that Schumacher discloses each of the items with the exception of the thermometer. (Office Action, page 8). However, as discussed above, Schumacher does not disclose, teach, or suggest an underpad/bed liner, a sanitary napkin, a specimen pan for receiving human tissue, a container for holding fetal remains for legal disposition, or a thermometer.

Gallo does not cure the disclosure deficiencies of Schumacher. Because Gallo is directed to treating the discomfort of children and/or infants, Gallo does not contain the items recited in claim 38 directed to assisting a woman during a miscarriage. There is nothing disclosed, taught, or suggested in Gallo that could be equated with an underpad/bed liner, a sanitary napkin, a specimen pan for receiving human tissue, or a container for holding fetal remains for legal disposition. Accordingly, the present disclosure is not obvious over Schumacher alone, or in combination with Gallo.

Moreover, it would not be obvious to one skilled in the art to modify the Schumacher kit to include a thermometer. The kit of Schumacher, as previously discussed, is a one-time cleanup kit used to clean up human waste. There would be absolutely no motivation to

include a thermometer in the clean-up kit of Schumacher. The Examiner provides no reasoning as to the motivation for modifying Schumacher beyond the short conclusory statement that "it would therefore be obvious to one of ordinary skill in the art at the time of invention [sic] to provide the kit of Schumacher with a thermometer, as taught by Gallo, for the monitoring of temperature." (Office Action, page 8).

The Examiner fails to indicate whose temperature would need to be taken when the Examiner asserts it would be obvious to modify Schumacher in view of Gallo. Schumacher is directed to cleaning up a one-time human waste spill. There would be no need or use for a thermometer in that context. As such, there would be no motivation to modify Schumacher with the teachings of Gallo, and further because each of the limitations found in claim 38 are not disclosed in Schumacher alone, or in combination with Gallo, claim 38 is patentable over Schumacher in view of Gallo.

Dependent Claim

Claim 39 depends from claim 38 and is therefore patentable for at least the same reasons, and further in view of its additional recitation.

(H) CONCLUSION

For the reasons set forth above, Appellant respectfully requests reversal of the Examiner's rejections.

This response is being submitted on or before April 17, 2009, with the required fee, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420

Respectfully submitted,

DORSEY & WHITNEY LLP  
**Customer Number 25763**

Date: October 4, 2010

By: Alicia Griffin Mills  
Alicia Griffin Mills, Reg. No. 46,933  
(612) 492-6514

(viii) CLAIMS APPENDIX

I claim:

1. (Previously Presented) A miscarriage kit comprising:

at least one under pad/bed liner configured to be positioned on a surface, the under pad/bed liner having a bottom layer and a top layer, wherein the top layer is designed to absorb bodily fluids, and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer;

at least one sanitary napkin;

at least one towel;

at least one pair of gloves;

at least one specimen pan for receiving human tissue; and

at least one container for holding fetal remains for legal disposition.

2-9. (Canceled).

10. (Withdrawn) An apparatus for use with miscarriages, comprising:

at least one under pad/bed liner;

at least one sanitary napkin;

at least one towel;

at least one pair of gloves;

at least one specimen pan; and

at least one container for holding pregnancy remains.

11. (Withdrawn) A method of dealing with a miscarriage, once it has been determined that a pregnancy is ending, likely to end, or has ended in miscarriage, the method comprising:

facilitating a woman's access to items that will assist her in dealing with her miscarriage.

12. (Withdrawn) The method of claim 11, wherein the act of facilitating is achieved by providing the woman with a miscarriage kit including the items.

13. (Withdrawn) The method of claim 11, wherein the act of facilitating is achieved by providing the woman with a list reciting the items.

14. (Withdrawn) The method of claim 13, further comprising taking the list and obtaining some of the items recited on the list.

15. (Withdrawn) The method of claim 11, further comprising the act of providing at least one item to deal with body fluids discharged from the woman due to the miscarriage.

16. (Withdrawn) The method of claim 12, further comprising the act of providing at least one item to deal with fetal tissue discharged from the woman due to the miscarriage.

17. (Withdrawn) The method of claim 11, further comprising providing at least one item relating to protection of bedding from body fluids or fetal tissue discharged from the woman due to a miscarriage.

18. (Withdrawn) The method of claim 17, further comprising providing at least one item to assist in collecting any body fluids discharged from the woman due to the miscarriage.

19. (Withdrawn) The method of claim 18, wherein the provided item to assist in collecting any body fluids discharged from the woman due to the miscarriage may be for use with body fluids discharged before, during, or after a miscarriage.

20. (Withdrawn) A method of claim 11, wherein the act of facilitating comprises providing a miscarriage kit.

21. (Withdrawn) A method of dealing with a miscarriage outside a medical facility, once it has been determined that a pregnancy is ending, likely to end, or has ended in miscarriage, the method comprising:

facilitating a woman's access to items that will assist her in dealing with her miscarriage outside a medical facility.

22. (Withdrawn) The method of claim 21, wherein the miscarriage is to be dealt with in a residential home.

23. (Withdrawn) The method of claim 21, wherein the act of facilitating is achieved by providing the woman with a miscarriage kit including the items.

24. (Withdrawn) The method of claim 21, wherein the act of facilitating is achieved by providing the woman with a list reciting the items.

25. (Previously Presented) The kit of claim 1, wherein the container for holding pregnancy remains is a spill-proof, sanitary container.

26. (Previously Presented) The kit of claim 1, further comprising a list of one or more items for use in helping the human in at least one of managing, controlling, cleaning up, handling, acquiring samples of, and disposing of the body fluids discharged before, during, or after a miscarriage based on the human's going through a miscarriage.

27. (Previously Presented) The kit of claim 1, further comprising one or more items used in helping the human in at least one of managing, controlling, cleaning up, handling, acquiring samples of, and disposing of the body fluids discharged before, during, or after a miscarriage based on the human's going through a miscarriage.

28. (Previously Presented) The kit of claim 1, further comprising one or more items used in helping the human in at least one of managing, controlling, cleaning up, handling, acquiring samples of, and disposing of the body fluids discharged before the human experiences a miscarriage.

29. (Previously Presented) The kit of claim 1, further comprising one or more items used in helping the human in at least one of managing, controlling, cleaning up, handling, acquiring samples of, and disposing of the body fluids discharged substantially during the period the human experiences a miscarriage.

30. (Previously Presented) The kit of claim 1, further comprising one or more items used in helping the human in at least one of managing, controlling, cleaning up, handling, acquiring samples of, and disposing of the body fluids discharged after the miscarriage.

31. (Previously Presented) The kit of claim 1, wherein the human tissue comprises fetal remains.

32. (Canceled).

33. (Canceled) The kit of claim 1, wherein the under pad/bed liner comprises an absorbent padding on the top surface and an impermeable backing on the bottom surface.

34. (Canceled).

35. (Previously Presented) A miscarriage kit comprising:  
at least one under pad/bed liner configured to be positioned on a surface, the under pad/bed liner having a bottom layer and a top layer, the top layer is designed to absorb bodily fluids, and wherein the bottom layer protects the surface from bodily fluids that soak through the top layer;  
at least one sanitary napkin;  
at least one towel;  
at least one pair of gloves;  
at least one specimen pan, wherein the specimen pan is configured to fit inside the rim of a toilet and further includes an upper rim configured to allow the upper rim to rest atop the toilet rim, the specimen pan having an opening positioned and sized to receive fluids and human tissue from a miscarriage, and wherein the specimen pan is comprised of a durable material; and wherein the specimen pan provides a measurement guide for measurement of fluid loss; and  
at least one container for holding fetal remains for legal disposition, wherein the container is opaque.

36. (Previously Presented) The miscarriage kit of claim 35, wherein the measurement guide allows the woman to measure fluid loss to assist her doctor in diagnosing a hemorrhage.

37. (Previously Presented) The miscarriage kit of claim 35, wherein the measurement guide shows one or more of the following measurements in any combination  
fluid ounces;

cubic centimeters (cc);

38. (Previously Presented) A miscarriage kit comprising:  
at least one under pad/bed liner;  
at least one sanitary napkin;  
at least one towel;  
at least one pair of gloves;  
at least one specimen pan for receiving human tissue; and  
at least one container for holding fetal remains for legal disposition; and  
at least one thermometer.

39. (Previously Presented) The miscarriage kit of claim 38, further comprising at least one protective undergarment.

40. (Previously Presented) The miscarriage kit of claim 1, wherein the bottom layer of the under pad/bed liner is impermeable to bodily fluids.

41. (Previously Presented) The miscarriage kit of claim 1, wherein the bottom layer of the under pad/bed liner is polypropylene.

42. (Previously Presented) The miscarriage kit of claim 1, wherein the under pad/bed liner further comprises a non-skid feature.

(ix) EVIDENCE APPENDIX

None.

(x) RELATED PROCEEDINGS APPENDIX

None.